UNITED STATES ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY

ARMY MEDICAL MATERIEL DEVELOPMENT ACTIV
FORT DETRICK
FREDERICK, MARYLAND 21701-5009

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U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY, 1987 ANNUAL REPORT

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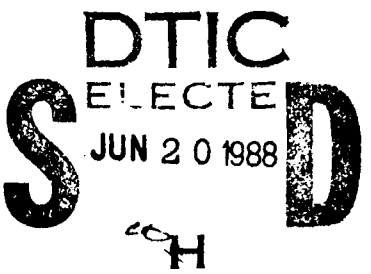

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
FORT DETRICK
FREDERICK, MARYLAND 21701-5012

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The Annual Report, Calendar Year 1987, summarizes development projects monitored by the U.S. Army Medical Materiel Development Activity in projects authorized by The Surgeon General, the Army, and the Commander, U.S. Army Medical Research and Development Command, and supported by RDTE funds from the U.S. Army Medical Research and Development Command.

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USAMMDA
1987 ANNUAL REPORT

CONTENTS

INTRODUCTION

The information contained within this annual report is a synthesis of the accomplishments of the staff of the U.S. Army Medical Materiel Development Activity (USAMMDA) during calendar year 1987. The Activity has continued to mature since its inception in 1984 and has successfully confronted the many frustrations intrinsic to its mission responsibilities. Orchestration of the exceptionally complex life cycle system management of medical materiel has been and continues to be a major undertaking.

While the role of the Army medical materiel developer is spelled out in pertinent regulations, the medical community often interprets those documents differently. Precisely just who develops or modifies medical equipment is frequently in the eye of the beholder. It is routinely the U.S. Army Medical Research and Development Command (USAMRDC) which is subjected to criticism when a medical development system fails to be fielded; however, senior leadership must be aware of the tortuous matrix of interactions required to field products. These issues become even more complex when Joint Service interests are taken into account. A notable example is the High Capacity Field X-Ray System.

During this past year, this product development was streamlined and met or exceeded all requirements placed on it. Unfortunately, major program decrements in the procurement funding line may prevent the integration of this critical technology into the field medical system. Therefore, while the Command successfully executed its development responsibility, it may fail in its mission to equip the force with a needed product. Mandated budget decrements are outside the span of control of this organization.

Only by intensive efforts of the conscientious staffs of the USAMMDA, Academy of Health Sciences (AHS), and the U.S. Army Medical Materiel Agency (USAMMA), can items be made available to our field medical units. The process by which we must develop and acquire equipment appears to be neither cost effective nor an efficient way to conduct business. While the life cycle system management model may not be broken, it is clearly cumbersome and inefficient. During the next year, we plan to examine closely the entire continuum of new AMEDD equipment acquisition from development through fielding in an effort to clearly identify duplication, redundancy, inefficiencies, and bureaucratic stumbling blocks to the expeditious fielding of the finest state-of-the-art medical equipment for our soldiers. Perhaps we can

contribute in some way in taming a system which has taken control of us all.

PROJECT MANAGEMENT

INTRODUCTION

The Project Management Support Division (PMSD) provides centralized administrative, financial management, contracting, and logistical support to the Project Managers and staff.

NEW MISSIONS

In September 1987, the Program Executive Office (PEO) concept for Health Care Systems was established to implement direction provided in the Defense Reorganization Act of 1986 and DOD Directive 5134.1. The Program Executive was identified as LTG Quinn Becker, The Army Surgeon General, and the Deputy Program Executive was identified as BG Richard T. Travis, with both to be supported by an office attached to USAMMDA. The mission of the PEO is to assure complete and comprehensive planning of resource requirements for acquisition, so that manpower, dollars, equipment, and facilities are available for execution of AMEDD missions during both peacetime and mobilization operations. This effort will be executed through the Program Managers for Combat Systems, Deployable Medical Systems, and Hospital Systems. Each of the System Managers will be supported by staff not included in PEO manpower requirements or authorizations.

MAJOR ACTIVITIES

- The FY87 Medical RDA Mission Area Materiel Plan (MAMP) Conference was convened 25-26 August 1987 to conduct product assessments necessary for evaluating the USAMRDC Research, Development, and Acquisition (RDA) Program. BG Travis opened the conference with an overview of the new PEO concept and its anticipated impact on current organizations and functions. Representatives from The Office of The Surgeon General (OTSG), USAMRDC, and USAMMDA considered 121 products against 28 Medical Mission Area Development Plan (MADP) deficiencies, and 15 medical-related Battlefield Development Plan (BDP) deficiencies contained in the 1987 Training and Doctrine Command (TRADOC) BDP. Assessment teams generated a ranked list of products. AMEDD prioritization was developed and this prioritization was approved by the Commanding General, USAMRDC. Several significant enhancements in the conference process were made, resulting in a more streamlined approach and applicable final report.

- USAMMDA sponsored two symposia this year. The first, Applied Medical Devices Symposium: Development and Fielding, was held in October at the Xerox Training Center near Leesburg, Virginia and was attended by over 100 participants. The purpose was to provide managers a forum for discussing the challenges associated with developing and fielding military medical devices. Participants represented the materiel developer, combat developer, logistician, tester, and trainer.

The second, also held in October, was the Paul M. Lish Pharmaceutical and Biological Regulatory Affairs Symposium, held at the Sheraton Inn, Frederick, Maryland, attended by approximately 80 scientists and managers representing all three Services. The purpose of the meeting was to discuss recent changes in Food and Drug Administration (FDA) regulations as they relate to the development and fielding of military-unique pharmaceutical/biological products.

- A Memorandum of Agreement (MOA) was established between USAMRDC and the U.S. Army Armaments, Munitions and Chemical Command (USAMCCOM) for readiness and fielding issues associated with items developed by USAMRDC and transitioned to USAMCCOM for operating support. The MOA was initiated to properly hand off the completed Decontaminating Kit, Skin: XM291 (SDK) at Milestone III. The significance of this MOA is that it established a formal means for interfacing between the two commands so that action officers can successfully accomplish requisite tasks.

- During 1987, USAMMDA procured Zenith Desk Top Computers to increase automation and better utilize commercial software. To promote greater compatibility between USAMMDA, USAMRDC, and other activities, each computer was equipped with standard software packages: a terminal emulation package (ST240), a spread sheet package (Lotus 1-2-3), and a data base package (dbase III). In addition, a "MegaTape" tape backup system was installed on the in-house VAX system to allow scheduled back-ups with minimum staff intervention.

Contractor development of the Project Management Control System (PMCS) continued toward full implementation. The Baseline Product List (BPL) module was brought to a fully functional stage with the implementation of Graphics, Data Entry enhancements, and a new Information Paper Report. The Schedule Module "user friendly" front end was completed. Training sessions were provided by the contractor on BPL and on the enhancements to the Schedule Module.

FISCAL PERFORMANCE

USAMMDA in-house fiscal execution exceeded DA established targets for fiscal year 87.

	Allotment	Obligations	Disbursements
Dollars (000)	$4,386	$4,099	$2,414
Target		90%	50%
Actual		93%	55%

Performance in the command-wide development program was not as successful. Generally, laboratory performance was far below target in terms of obligations, such that the successful execution of the extramural program could not pull the total line above target. However, the more critical disbursement targets were met.

		Percent					
	Allotment	In-House		Extramural		Total	
Project	($000)	OBL	DISB	OBL	DISB	OBL	DISB
836	11,403	75	50	92	42	89	43
808	6,225	84	49	97	20	90	36
809	8,913	52	37	96	59	83	53
993	23,195	88	58	92	41	91	43
Total 6.3B	49,736	76	49	93	42	89	44
832	1,746	89	64	92	35	90	47
847	7,219	69	55	82	63	79	61
848	9,094	92	26	92	86	92	84
849	2,559	87	54	78	38	81	43
Total 6.4	20,618	80	54	87	70	86	68
Total Program	70,354	77	50	91	51	88	51

MANPOWER ACCOUNTING

In August 1987, USAMMDA implemented an update of the Manpower Accounting System (MANAS) that fully integrates automated input from the PM offices with work hour allocation algorithms and reports to meet accounting and management requirements. The revised system, written in ORACLE DBMS, is fully compliant with AR 70-6 and will be integrated with the Committment Accounting System in 1988 to eliminate current requirement for manual input of approximately 150 entries per month.

PERSONNEL ACCOUNTING

In November 1987, USAMMDA installed and populated a fully integrated Manpower and Personnel Tracking System. The system, initially written and tested at U.S. Army Biomedical Research and Development Laboratory, (USABRDL), will allow for visibility and control of TDA positions, authorizations, and personnel vacancies at very detailed levels as well as maintain biographical information.

USAMMDA KEY PERSONNEL

Position	Name	Date
Commander	COL C.E. Pedersen, Jr.	10 Sep 87 to 31 Dec 87
	COL H.G. Dangerfield	1 Jan 87 to 10 Sep 87
PM/AMSPMD	COL B.A. Schiefer	3 Aug 87 to 31 Dec 87
	Dr. D. W. Caldwell (Acting)	30 May 87 to 2 Aug 87
	COL H.C. Johnson	1 Jan 87 to 29 May 87
PM/BSPMD	Dr. W.E. Brandt	9 Aug 87 to 31 Dec 87
	COL D. Robinson	1 Jan 87 to 2 Jun 87
PM/PSPMD	LTC R.O. Pick	20 Oct 87 to 31 Dec 87
	LTC G.L. Wannarka	1 Jan 87 to 20 Oct 87
CH/PMSD	LTC R.H. Perry	1 Jul 87 to 31 Dec 87
	LTC M.D. Barbour	1 Jan 87 to 30 Jun 87

USAMMDA STRENGTH

As of 31 December 1987:

	Military	Civilian	Total
Required	38	55	93
Authorized	23	34	57
Actual	20	28	48

BIOLOGICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

INTRODUCTION

The Biological Systems Project Management Division manages the development and acquisition of biological products to prevent casualties or loss of soldier effectiveness due to disease. These diseases may be naturally acquired (close contact, unsanitary conditions, contaminated environment, biting insects), or delivered deliberately (aerosols). Product Officers exploit domestic and foreign medical technology to remedy deficiencies identified by the Combat Developer and monitor research projects for their application to disease protective measures.

MILITARY RELEVANCE

Casualties from disease have been a major cause of hospital admissions and ineffectiveness on the battlefield. Figures for admission for soldiers during one year in Vietnam were as follows: disease - 70.6 percent; battle casualty - 15.6 percent; nonbattle injury - 13.8 percent. Efforts to reduce the impact of disease on operations will make a significant contribution to soldier effectiveness.

AIMS AND OBJECTIVES

This Division's directive is to develop effective preventive measures against diarrheal diseases; malaria; acute respiratory diseases; hepatitis; insect-transmitted diseases such as dengue and Japanese encephalitis; hemorrhagic fevers and other diseases spread by aerosol; schistosomiasis; meningococcal disease; and opportunistic wound infections. Methods to address these deficiencies (some of which include treatment) are vaccines, immune enhancers, adjuvants, immune globulins, antiviral drugs, and insect repellents.

PROJECT DESCRIPTIONS

- The <u>Insect/Arthropod Repellent System</u> consists of: a) an extended duration chemical treatment for Battlefield Dress Uniform (BDU) to provide maximum protection from bites for areas of the body covered by the uniform; and, b) an extended duration, topically applied repellent that is user acceptable, operationally practical, and provides maximum protection from bites of

insects and other arthropod vectors of disease. The system is in the final phase of development. Additional documentation of efficacy was provided by Air Force personnel in testing against heavy mosquito biting in Alaska. Volunteers using both the topical repellent and clothing treatment averaged only one bite per hour, while controls endured a rate of 1149 mosquito bites per hour.

- The Biological Agent Identification and Diagnostic System, Rapid, Field is a rapid ID system used to indicate the presence of, or exposure to, a wide spectrum of biological agents that might be encountered in the course of military operations. USAMRDC laboratories and the Human Engineering Laboratory, Aberdeen Proving Ground, MD, provided Technical Test data on the rapid identification prototype systems delivered in May 1987. Contracts awarded under this project have produced purified reagents for consistency to be used as the system matures.

- N. meningitidis (Group B) Vaccine is a protein-based vaccine for use in conjunction with licensed polysaccharide vaccines to protect military personnel against epidemic cerebrospinal meningitis. A 3-year grant for testing was implemented with the Pan American Health Organization (PAHO) in April 1987. A team from the Chilean Ministry of Health, PAHO, and Walter Reed Army Institute of Research (WRAIR) set up a field station; and from July to October 1987, immunized 40,000 volunteers in a double blind study. Controls received a licensed Group C vaccine.

- The Live Attenuated Chikungunya Vaccine, produced in cultured cells, will protect troops against natural infection or Biological Warfare (BW) use of Chikungunya virus. Phase I testing of the Chikungunya vaccine in 28 volunteers was successfully completed at United States Army Research Institute of Infectious Diseases (USAMRIID) during 1987. A Joint Services Operational Requirement (JSOR) was drafted in July 1987 and is being staffed through TRADOC.

- The Live Attenuated Dengue Type 4 Vaccine will be combined with one or two other attenuated dengue virus serotypes to prevent dengue (breakbone) fever. Phase I testing of this vaccine developed at WRAIR began in October 1987. No adverse effects have been noted. A Capstone JSOR for dengue vaccines was drafted in November 1987 and is being staffed through AHS.

- The Japanese Encephalitis Killed Vaccine (extracted and purified from mouse brain tissue), will protect military personnel against Japanese Encephalitis. A request for indemnification for Biken, the manufacturer of the killed Japanese encephalitis vaccine (required by the company for sale of the vaccine in the U.S.), was approved by the Secretary of the Army. A Capstone JSOR for Japanese encephalitis vaccine was drafted in November 1987 and is being staffed through the AHS.

- The Klebsiella Polysaccharide Vaccine is a bacterial product which will produce immune globulins to treat opportunistic infections in burn-wound patients. The Klebsiella polysaccharide vaccine underwent testing in 73 volunteers in a Phase II clinical trial at Fort Lewis, WA, in September and October. The vaccine was well tolerated and induced an excellent antibody response. This was USAMMDA's initial effort at using the Test Schedule and Review Committee (TSARC) process to obtain access to volunteers.

- The Pseudomonas Polysaccharide Vaccine is also a product extracted from bacteria and injected into volunteers to produce immune globulins to treat opportunistic infections in burn-wound patients. An application for an Investigational New Drug (IND) exemption for the Pseudomonas polysaccharide vaccine was submitted and reviewed by the FDA. Phase I clinical testing was completed. USAMMDA obtained a decision to allow the use of the TSARC process to obtain access to United States Army Forces Command (FORSCOM) units for the purpose of soliciting volunteers for drug and vaccine testing.

- Botulinal Toxoids, Types F & G will be used in a polyvalent product designed for administration to military personnel being deployed to an area where there is a potential threat use of Clostridium botulinum toxin as a BW agent. A Request for Proposal (RFP) for scale up of Types F & G Botulinal toxoids was issued, the Source Selection Board met, and contract negotiations are in process.

- The Q Fever Vaccine is an inactivated product for administration to individuals at risk of contracting Q fever or for military personnel being deployed to areas where there is a potential threat use of Coxiella burnetti as a BW agent. Preclinical testing of a candidate Q fever vaccine was initiated. A JSOR for Q fever vaccines was staffed and is awaiting final approval.

- The Tularemia Vaccine is designed for administration to military personnel being deployed to an area where there is a potential threat use of Francisella tularensis as a BW agent. Protocols have been submitted and approved for Phase I clinical testing of new lots of tularemia vaccine produced under a modified procedure. The studies will test the safety of the new lots and compare the new vaccine with the old product. Animal data suggest that the two vaccines are essentially identical.

- The Hepatitis A Killed Vaccine produced in cultured cells will be administered to all military personnel to decrease the incidence of Hepatitis A.

- An Adenovirus Vectored Hepatitis B Vaccine will be produced by using live adenovirus type 7 vaccine (in use in basic recruit camps) genetically engineered to produce Hepatitis B antigen. Recipients of this vaccine should develop immunity to both Hepatitis B and adenovirus type 7.

- Vaccinia Vectored Venezeulan Equine Encephalitis Vaccine (VEE) will be produced by insertion of VEE genes that direct the production of immunizing antigens into the live attenuated vaccinia virus presently used for smallpox immunization. Recipients of the vaccine will be protected against both VEE and smallpox. An interagency agreement between the USAMRDC and the Centers for Disease Control (CDC) regarding vaccinia vectored Venezuelan equine encephalitis vaccine was signed. The appropriate VEE virus genes have been inserted into vaccinia and the recombinant virus induces protection from lethal VEE infection in test animals. The cell-mediated immunity induced in mice is as potent as that induced by natural VEE infection.

- Ribavirin, a broad spectrum antiviral drug, has been shown to be effective against hemorrhagic and sandfly fevers. Efficacy studies against other viruses of military interest are in progress.

- A live attenuated Argentine Hemorrhagic Fever Vaccine, produced in cultured cells, is being studied through a grant awarded to the PAHO. Volunteer studies are in progress in Argentina to determine efficacy of the Candid #1 vaccine in both immune and nonimmune populations.

- Shigella Vaccines are oral products containing live bacteria with specific antigens to protect against diarrheal diseases. A grant was awarded to the Israeli Defense Forces to conduct epidemiological surveillance for diarrheal diseases and hepatitis.

- Lassa Fever Immune Plasma is an immune globulin used to treat Lassa fever infections. The collection of human immune plasma in Africa is an ongoing contract effort. Studies were completed to evaluate the method for globulin preparation from Lassa immune plasma to ensure that there is no contamination with AIDS virus or hepatitis.

- Stroma Free Hemoglobin is an oxygen-carrying blood substitute for use in field medical units. Baxter-Travenol produced several batches of cross-linked hemoglobin that were evaluated for biological and chemical properties. This stroma-free hemoglobin appeared to be nontoxic; however, there are some problems with stability, nonreproducibility (lot-to-lot variation), rapid conversion to methemoglobin, and varying opinions on suitable animal models for efficacy testing.

- Schistosome Topical Antipenetrant (TAP) is a lotion, based on the anthelmintic niclosamide. The Schistosome TAP lotion was successfully tested for efficacy against Schistosoma mansoni in Cebus monkeys at the University of Lowell, MA. Working groups were convened to outline clinical testing of the TAP and to finalize the draft Capstone JSOR document for Individual Protection Against Schistosomiasis.

- The Plasmodium falciparum Sporozoite Vaccine was developed from the circumsporozoite protein (CSP) gene of the sporozoite state of P. falciparum. In human testing, an individual with the highest antibody titer was protected from P. falciparum introduced by bites of laboratory-infected mosquitoes. The FSV-1 vaccine has been combined with adjuvants and encapsulated in liposomes to enhance immunogenicity. An IND was filed for an FSV-2 vaccine and Phase I studies were initiated. Additionally, a Joint Working Group (JWG) was held at the AHS to finalize the draft Capstone JSOR for Malaria Vaccines.

- The Plasmodium vivax Sporozoite Vaccine was developed from the circumsporozoite protein (CSP) gene of the sporozoite stage of P. vivax.

- The Antimalarial Drug, Qinghaosu is produced by extraction and purification of the substance artemisinin (qinghaosu) from the plant Artemisia annua. An initial 2 kg of qinghaousu were procured and converted, under GLP-GMP conditions, to the artemisinin analog arteether. An oil-based formulation of qinghaosu for intramuscular use has been prepared and is currently undergoing preclinical toxicology testing in a joint USAMRDC-World Health Organization (WHO) venture.

- Liposome-Encapsulated Pentostam is a safer, more effective formulation of Pentostam for the treatment of visceral leishmaniasis. Liposome-encapsulated Pentostam was included in a Draft Capstone JSOR for Antileishmanial Drugs finalized at a JWG held at the AHS.

- The Salk Institute Vaccine Production Facility is a manufacturing facility dedicated exclusively to the production of vaccines and diagnostic reagents under federal regulatory guidelines. This facility will be managed by the USAMMDA in 2Q88 under a task order arrangement.

- The University of Maryland Vaccine Testing Facility is used for evaluating vaccines in human safety and efficacy trials. The facilities at the contractor's location, including the 22-bed isolation ward, make this a unique resource for evaluating vaccines developed by Army labs or by extramural contractors. By operating the contract as a task order, development costs can be attributed to each vaccine product in clinical studies. All costs associated with medical care required as a proximate result of participation in these vaccine testing studies will be borne by the Army.

MAJOR ACCOMPLISHMENTS

- Operational testing (OT II) at Fort Stewart, Georgia, in August 1987 demonstrated efficacy and good user acceptance of the topical repellent and the Individual Dynamic Absorption method for impregnating BDUs with permethrin. Application for Environmental Protection Agency (EPA) registration of the topical repellent was filed in May 1987.

- A Phase II clinical trial of the killed Hepatitis A vaccine developed at WRAIR was initiated at Fort Lewis, WA, in October.

- The live virus recombinant **adenovirus vectored Hepatitis B vaccine** has been produced under GLP/GMP guidelines and is undergoing preclinical testing at Wyeth Laboratories.

- A task order contract for a vaccine testing facility was initiated with the **Center for Vaccine Development at the University of Maryland.** Indemnification for testing was approved by the Secretary of the Army.

- Data from a 2-year field trial in China were assessed to determine efficacy of **ribavirin in treating** Hemorrhagic Fever with Renal Syndrome (HFRS). Marginal significance was demonstrated in preventing death when treated groups were compared with placebo controls. Two sections of the New Drug Application (NDA) were submitted to the FDA for review.

- A Technical Working Group held 18 August 1987 recommended that only one contractor for the **Rapid ID System** continue in the Demonstration and Validation (D/V) Phase for an additional 12 months because its ELISA technology was most promising and was aligned with USAMRDC laboratory efforts.

- A Phase I study of the **FSV-1 malaria vaccine was** completed at WRAIR.

- The gene coding for the circumsporozoite antigen of P. vivax was expressed in Escherichia coli and the resulting antigen was purified by researchers at Smith Kline and French Laboratories collaborating with the Army. Successful completion of preclinical studies led to the filing of an IND. The P. vivax **sporozoite vaccine** was included in the Capstone JSOR for Malaria Vaccines.

- A new, less reactogenic **Q fever vaccine is** presently being produced and safety tested at the Salk Vaccine Production Facility. Diagnostic spot slides for the hemorrhagic fever viruses were made at Salk and represent the only source of these materials. Monoclonal antibodies were produced as research reagents for USAMRIID and WRAIR, and as reagents for quality control of live attenuated vaccines.

PROJECTIONS

- An EPA decision on permethrin as a **clothing impregnant** in the Insect/Arthropod Repellent System is pending, and issues regarding methods of treatment for the BDU will be addressed by a JWG in April 1988. EPA approval of the topical repellent is expected during 1988.

- The code on the N. meningitidis (Group B) vaccine will be broken at the end of the surveillance period when it has been determined how many cases of Group B disease have occurred among the volunteers.

- Data on mosquito uptake of the **Chikungunya vaccine** virus will be collected at USAMRIID, a requirement before initiation of Phase II studies.

- Larger doses of **Dengue 4 vaccine** will be tested in volunteers for safety studies.

- The Army and the FDA will encourage and assist the Japanese to license the **Japanese encephalitis vaccine** in order to eliminate the requirement for extensive record keeping.

- WRAIR is working with civilian vaccine developers to enhance the antigenicity of the **Hepatitis A vaccine**, possibly allowing a further reduction in the number of doses required for protection.

- The **Klebsiella polysaccharide vaccine** will undergo large-scale testing in a cooperative study between the WRAIR and the Veteran's Administration.

- A Phase II trial of the **Pseudomonas polysaccharide vaccine** is scheduled for March 1988 at Fort Hood, TX.

- An award for production of **botulinal toxoids** is expected in mid-1988. The contract is expected to cover a 3-year period.

- An IND for the **Q fever CMR vaccine** should be submitted in 3Q88, with initial clinical testing to follow soon thereafter.

- A Scientific Steering Committee meeting will address the practicality of licensing the **tularemia vaccine** following Phase I testing of the new lots.

- The IND for the adenovirus-vectored hepatitis B vaccine is scheduled for submission in April 1988, and the Phase I testing is scheduled for May 1988 at the University of Maryland Vaccine Testing Facility.

- It will be determined if the Vaccinia vectored VEE vaccine induces protection against lethal challenge of the seven subtypes of VEE virus, and whether the genes inserted into the vaccinia vector have any effect on the immune response to vaccinia. The horse is the lethal target of the virus in nature and the recombinant vaccine will be tested in this large animal in the coming year.

- At least three vaccines are scheduled for testing at the University of Maryland Vaccine Testing Facility: two live recombinant bacterial vaccines against diarrheal diseases, and the recombinant adenovirus-hepatitis B vaccine.

- The ribavirin data from the China studies will be evaluated to determine if they can be interpreted as two studies since several study sites were used. The FDA insists on two separate studies. Additional clinical studies may be required for HFRS as well as for any other diseases such as Lassa fever.

- In addition to obtaining larger numbers of volunteers to receive the Argentine hemorrhagic fever vaccine, the PAHO grant includes rodent trapping studies and a treatment regimen employing the antiviral drug ribavirin. Consultation and rodent trapping will be provided by the faculty of Johns Hopkins University.

- Bacteria-vectored shigella vaccines will continue to be evaluated. Additional lots of the E. coli -S. flexneri vaccine will undergo preclinical studies prior to human testing. Serologies from Israeli recruits will be used to measure exposure rates. Data collected from these studies will be used to plan field trials for vaccines that have been developed including Shigella vaccine, hepatitis vaccine, and vaccines for opportunistic pathogens (Klebsiella and Pseudomonas).

- Purified immune globulins to the lethal Lassa fever virus can now be prepared by the method that assures that no hepatitis or HIV (AIDS) viruses will contaminate the final product.

- It is planned to return the **stroma-free hemoglobin** project to the research laboratory since the characteristics of the product are not yet close enough to the Combat Developer's operational requirements.

- The Statement of Work for an extended D/V contract period will address deficiencies in the **Rapid ID System** and approaches that reflect the latest technology, e.g., a 1-to-2 step assay in a paper, card, or "dipstick" format that provides results within 15 minutes. Delivery of a prototype system, meeting military specifications and performance criteria, is projected by June 1989.

- The following additional toxicology studies have been scheduled to complete the data required for an IND for the **Schistosome topical antipenetrant**: 90-day dermal toxicity studies of niclosamide in guinea pigs and rabbits and a phototoxicity study of niclosamide in mice. Progress depends on contractor efficiency. An RFP is being prepared for release in late 1988 for the Phase I testing in humans.

- Other P. falciparum **sporozoite vaccines** consisting of different CSP constructs, carriers, and adjuvants are being evaluated. Preclinical studies of all of the above combinations are continuing. An IND for synthetic peptide vaccines is currently in preparation. Phase II laboratory efficacy studies of promising vaccines will be pursued and hopefully will identify a viable FSV vaccine for field studies.

- Phase I studies of the P. vivax **sporozoite vaccine** will begin in 1988.

- A patent application is being prepared for a water soluble form of **artemisnin (qinghaosu)** for intravenous use. This should be more effective against cerebral malaria. The recent acquisition by USAMMDA of 2 kg of artemisinin should be converted to the water soluble derivative for preclinical studies required for an IND.

- Under a no-cost agreement with the Wellcome Foundation (producers of Pentostam), preclinical studies will be planned for the cooperative development of **liposome-encapsulated Pentostam**. Wellcome will provide the GMP lipsome/Pentostam formulation and USAMRDC will be responsible for completion of preclinical studies and clinical testing of the drug. Additionally, Wellcome will assemble the IND. A primate toxicity study of the proposed liposome/Pentostam formulation will be initiated

in January 1988. Preclinical data are currently being assembled for the first draft of the IND.

- Final production of the new Q fever vaccine at Salk facility will be completed in 1988. In addition to continued production of diagnostic reagents and certified cell lines, 100,000 dose lots of Rift Valley fever vaccine may be produced in 1988. Additional lots of Argentine hemorrhagic fever vaccine are anticipated and the facility will be used to produce live vectored vaccines.

PHARMACEUTICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

INTRODUCTION

The Pharmaceutical Systems Project Management Division centrally manages the development and the initial production of pharmaceutical products (antidotes and drugs), related drug delivery systems (autoinjectors and transdermal patches), and decontamination products. These products are fielded as preventive, protective, and therapeutic modalities for use against chemical and biological warfare threats, certain endemic diseases, and the treatment of combat casualties.

MILITARY RELEVANCE

U.S. military forces must be prepared to serve anywhere in the world against any threat. This could result not only in conventional injuries sustained during combat but exposure to chemical and biological warfare agents as well as exposure to endemic diseases not commonly found in the United States. The development of products against these threats will help save lives, sustain the fighting force, and enhance return to duty.

AIMS AND OBJECTIVES

The aims and objectives of this division are to develop pharmaceuticals to be used for prophylaxis, immediate treatment, and definitive treatment against a wide variety of naturally occurring diseases, threat force use of chemical and biological agents, and combat-generated injuries. These pharmaceuticals include those for use following exposure to organophosphorus compounds, vesicants, and cyanide, and those to protect or treat soldiers suffering from malaria, schistosomiasis, and leishmaniasis. In addition, a kit to decontaminate the skin following exposure to chemical warfare agents or toxins is undergoing development as is an antidote against the oral ingestion of toxins. From a more conventional aspect, blood replacement fluids, improved antimicrobial skin dressings, and more field-durable analgesics are under development.

PROJECT DESCRIPTIONS

- The resin-based Decontaminating Kit, Skin: XM291 (SDK) is being developed with Rohm and Haas for Joint Service use. A special Milestone I/II In-Process Review (IPR) 2Q87 resulted in a recommendation that the SDK be transitioned into Full Scale Development (FSD) upon approval of the JSOR. A development contract with production options was awarded, and an MOA between the USAMCCOM and USAMRDC was signed 2Q87 governing actions required to assure successful fielding of chemical defense items/systems. A Transition Planning and Tracking Group was chartered, the proposed JSOR for the SDK was approved in September 1987, and in October 1987, the Commander, USAMRDC, approved transition of the XM291 SDK to FSD. Five thousand prototype SDKs were manufactured and shipped to Department of Defense (DOD) and contractor testing laboratories for technical testing (TT) and evaluation. A Test Design Plan (TDP) for Initial Operational Test and Evaluation (IOT&E) has been prepared by the U.S. Armor and Engineer Board, and IOT&E is scheduled to begin 1 February 1988, at Fort Bragg, NC.

- USAMMDA was tasked by USAMRDC to reformulate British antilewisite for ophthalmic use. British Antilewisite, Improved Ophthalmic Formulation (I-BAL) is compatible with ophthalmic administration while maintaining good stability and minimal toxicity. The antidote will be used by the individual soldier primarily to treat eyes exposed to the vesicant lewisite and secondarily as a topical antidote to lewisite. Current technology can offer improvements in purity, stability, and local irritation, compared to the original formulation. The current concept indicates that the package will also contain a swab saturated in the drug for topical administration. A Capstone JSOR, (Family of Vesicant Antidotes) is being staffed. The Army Medical Department Technical Committee (AMDTC) has sanctioned the development of I-BAL. On approval by the Medical Systems Review Committee (MSRC), a steering committee will be established to provide input to the development process, and an RFP will be issued for reformulation, packaging, and testing.

- A Nerve Agent Anticonvulsant is required to prevent or ameliorate convulsions in severe nerve agent casualties. Anticonvulsants such as diazepam prevent nerve agent convulsions and brain injury. A JSOR was initiated by the AHS to develop and field a Nerve Agent Anticonvulsant (NAAC). A Tri-Service Strategy Meeting reviewed data on nerve agent convulsions, brain injury, and anticonvulsant drug candidates and recommended that

injectable diazepam be developed into an autoinjector and fielded as quickly as possible. The FDA identified diazepam as the most rapidly fieldable anticonvulsant. USAMMDA presented the diazepam autoinjector concept to the AMDTC. The NAAC will be issued only at Field Commander direction and will be used by troops only for buddy aid. A Test and Evaluation Master Plan (TEMP) was written and reviewed by a Test Integrated Working Group (TIWG); the draft JSOR has been forwarded to TRADOC for staffing. A Market Survey is underway, and an RFP is in preparation. The diazepam autoinjector is expected to be fielded by 1Q91.

- Hypertonic Saline Dextran (HSD) is a safe and effective, small-volume product suitable for rapid field administration that can be used to resuscitate and stabilize hypovolemic shock casualties. A No-Dollar Agreement was signed with Pharmacia. A Project Steering Committee (PSC) has been formed and clinical trials have begun in Houston and Denver (a third clinical site may become active). Preclinical studies will begin early next year at Letterman Army Institute of Research (LAIR). Evaluation of clinical effectiveness will be possible at the first data point after 175 patients have been enrolled.

- Halofantrine will be a safe and effective treatment and prophylaxis for P. falciparum malaria resistant to Mefloquine. All preclinical and clinical studies have either been completed or are nearing completion for a treatment indication. There is a No-Dollar Agreement with Smith, Kline and French (SKF) for joint development of the product. SFK is expected to file for regulatory approval in the U.S. this year. Evidence for a potential use of halofantrine for prophylaxis has been reviewed, and it is expected that a decision to enter this multiyear program will be made early in calendar year 1988.

- An improved Antimicrobial Dermal Dressing (ADD) will be capable of providing sustained release of antimicrobial agents at the site of dermal injury to prevent infection and enhance wound healing. An ADD is being developed in response to an operational need from the Special Operations Forces (SOF). The Combat Developer is preparing the draft JSOR while the Materiel Developer updates the market survey. A prototype dressing, impregnated with two antibiotics, has completed preclinical studies demonstrating safety and efficacy and will be ready for IND submission 3Q88. A TIWG will address OT/TT issues and review the TEMP. A Milestone I

In-Process Review (IPR) will be held 3Q88. Phase I clinical studies will begin 4Q89.

- **Morphine Repackaging** is needed to provide an analgesic with extended stability and greater durability to meet field requirements. Morphine stocks in the inventory are over 25 years old and are beginning to deteriorate. The AMDTC (in conjunction with AHS and USAMRDC) established criteria designed to identify and select an acceptable replacement injection device for the field and tasked USAMMDA to explore the use of tamper-proof syrettes for morphine. Market investigations found that there was no industrial base available in syrette technology. In December 1987, USAMMDA briefed the AMDTC requesting concurrence for a program to develop and field an injection device for morphine. The AMDTC granted AHS time for additional evaluation of the available options and requested that the recommended option be presented at the next AMDTC meeting.

- A New Drug Application (NDA) for the antimalarial drug, **Mefloquine Hydrochloride**, was filed with the FDA in February 1986. The indications contained in the NDA were for the prevention and treatment of chloroquine resistant *Plasmodium falciparum* malaria. At a November 1987 meeting between the FDA and the applicants, the FDA requested that the biopharmaceutical information of the NDA be reorganized and submitted as a supplement to facilitate rapid review. This task was accomplished and results submitted to FDA in December 1987. As of 31 December 1987, the NDA remains under review.

- A proposed **Toxin Antidote** is a commercially available activated charcoal preparation with three times the surface area of Activated Charcoal USP. Documented evidence shows that this product could be used as an antidote in a variety of poisonings, including mycotoxins. USAMRIID agreed to prepare available data for an MSRC meeting, and USAMMDA has conducted a market survey for product availability.

- A **Multichambered Autoinjector** (single barrel) for administration of nerve agent antidote (2 mg atropine, 600 mg 2-PAM Cl) is being evaluated. Prototypes were obtained from three manufacturers under No-Dollar Agreements and subjected to mechanical durability tests; two were found acceptable for further evaluation and field testing. A clinical study at the Department of Clinical Investigation, Madigan Army Medical Center, will determine whether injection of atropine and 2-PAM Cl into the same injection site will adversely affect absorption

as compared to administration using the MARK I kit (final report is expected 1Q88). A draft JSOR is being staffed and approval is expected 2Q88.

- Pyridostigmine Sustained Release is envisioned as a superior pretreatment for use against nerve agent poisoning. Program documents for the development of pyridostigmine were revised, updated, and staffed in preparation for a Milestone I IPR, 3Q88. Documentation for the IND file at the FDA was updated. An efficacy study of pyridostigmine has been completed to furnish the basis for establishing the benefit of pretreatment in conjunction with 2-PAM Cl and atropine against nerve agent poisoning. Subchronic 90-day studies on the effects of pyridostigmine were conducted (no untoward toxicities were found with repeated administration). No-Dollar Agreements were established to develop candidate formulations. Toxicological studies on the transdermal delivery indicated that pyridostigmine is an irritant and sensitizer to the skin and further attempts to overcome these toxicities were not successful; recommendation will be made to stop efforts for the transdermal delivery of pyridostigmine.

- Aerosolized Nerve Agent Antidote, Medical (MANAA) is being developed for medical personnel to use with nerve agent casualties as a follow-on to the autoinjector. A single-dose bioavailability study of atropine was conducted and the results indicated that MANAA was safe to administer in the formulation developed and that appropriate blood levels could be obtained. Since definitive efficacy studies cannot be done with this product, a petition was submitted to the FDA requesting a waiver from the normal efficacy requirements. This petition, the first of its kind ever submitted, is currently under evaluation by the FDA. If concurrence is obtained, a review of the safety data generated will be made and, if acceptable, an NDA will be filed by December 1988.

- Aerosolized Nerve Agent Antidote, Personal (PANAA) is being developed for issue to individual soldiers for administration of atropine through the protective mask. An RFP has been prepared; however, the results of the FDA review of the petition for MANAA, and the identification of possible contractors, have delayed the release of this RFP. Information as to the feasibility of this concept needs to be generated in order to transition this project to the Chemical, Research, Development, and Engineering Center (CRDEC) for final development.

MAJOR ACCOMPLISHMENTS

- The **Decontaminating Kit, Skin: XM291** was transitioned into Full Scale Development (FSD); a development contract with production options was awarded which will complete the efforts in this program. An MOU was signed between USAMRDC and USAMCCOM to establish procedures for certain chemical defense items.

- Three multichambered **autoinjectors** completed durability testing; one of these was used in a clinical study to determine the effects on absorption of the two ingredients, atropine, and 2-PAM Cl when injected into the same site.

- A consensus was reached among the Combat Developer, the Materiel Developer and the User that a requirement exists for an **Antimicrobial Dermal Dressing.**

- A petition, the first of its kind, was submitted to the FDA requesting a waiver from the normal requirements for efficacy for a chemical warfare antidote.

- A No-Dollar Agreement was signed for the joint development of **Hypertonic Saline Dextran** as a blood fluid replacement, and an IND was submitted to the FDA.

- Results of the **pyridostigmine** efficacy studies in primates were made available; these will furnish the basis for establishing the benefit of pyridostigmine in conjunction with atropine and 2-PAM Cl against nerve agent poisoning. Two No-Dollar Agreements were established to develop candidate formulations for clinical testing of pyridostigmine.

- Two new contracts for the conduct of toxicology studies in support of NDAs were awarded.

- The AMDTC sanctioned a program for the reformulation of **Ophthalmic British Antilewisite.**

PROJECTIONS

- A Milestone II/III IPR is scheduled for the antimalarial drug **halofantrine.**

- Clinical studies on two or three formulations of a **sustained-release pyridostigmine** will be concluded and a Milestone I IPR will be held.

- IOT&E will be conducted on the **Decontaminating Kit, Skin: XM291** by the U.S. Army Armor and Engineering Board. The JSOR for this project will be approved.

- A program to repackage **morphine** for field medic use will be sanctioned by the AMDTC.

- A special IPR will be held to discontinue efforts on a **transdermal** drug delivery system for **pyridostigmine.**

- An IND for one version of an **antimicrobial dermal dressing** will be filed, and clinical studies will begin.

- JSOR approval is expected for the multichambered **autoinjector**, and a Milestone I/II IPR will be held. IOT&E will be conducted.

- Clinical studies will be concluded, and the NDA will be submitted for the **Aerosolized Nerve Agent Antidote, Medical.**

- An RFP will be released, and a contract awarded for the development of the **Aerosolized Nerve Agent Antidote, Personal.**

- It is expected that AMDTC sanction will be given to initiate the anticonvulsant development effort.

- An RFP will be released and contractual effort begun on the **Ophthalmic British Antilewisite** program.

- A program will be initiated for the development of a **mycotoxin antidote.**

- The NDA will be approved for the antimalarial **Mefloquine**, and it will be transitioned to USAMMA.

APPLIED MEDICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

INTRODUCTION

The Applied Medical Systems Project Management Division is a multidisciplinary team with broad mission responsibilities to centrally manage the development and initial production of applied medical products, related diagnostic equipment, optical corrective devices for protective masks, and pesticide delivery systems.

MILITARY RELEVANCE

Applied Medical Systems is committed to developing compact, lightweight, durable medical equipment to achieve both the Army's demanding Service-unique and multi-Service mission requirements. Diverse, multi-discipline technologies are integrated to create a wide range of state-of-the-art systems. Equipment initiatives are directed toward addressing medical defense against chemical warfare agents, medical protection against military hazards, and the ability to provide care to the combat casualty.

AIMS AND OBJECTIVES

Army readiness is predicated upon the timely and successful execution of programs by the materiel developer. To achieve this goal, Applied Medical Systems capitalizes on emerging Tech Base efforts and aggressively manages the development component of the AMEDD RD&A process to meet DA and Joint Service performance and supportability requirements for field-survivable medical equipment.

PROJECT DESCRIPTIONS

- The **Military Transportable Field Radiographic and Fluoroscopic System (MTFRFS)** complies with all radiation health and safety standards and meets the requirements for operation in the Army field environment. Revalidation of the Letter Requirement for the MTFRFS was completed on 9 January 1987. All tasks related to safety or the correction of deficiencies noted during testing have been or will be accomplished. The IPR in March 1987 decided that more information on the status of the development was necessary before a Production and Deployment (P/D) decision could be made. A JWG held in April 1987 developed a plan of action for presentation to

the next session of the Milestone III IPR which recommended type classification, and limited production, and requested that a production cost proposal be presented at a Milestone IIIb IPR. The Surgeon General approved the type classification action, and the AMDTC concurred. An additional $10 million in Other Procurement, Army (OPA) funding was provided to secure a validated Level 3 drawing package and three initial production systems. A firm-fixed-price modification of the contract was negotiated and a production proposal was received from the contractor. An agenda package containing the procurement costs for the production units and the resolution of issues remaining will be prepared for the Milestone IIIb IPR scheduled for early 1988.

- The Resuscitation Fluids Production and Reconstitution Systems (REFLUPS) is a system to produce sterile Water for Injection (WFI) from an appropriate potable water source, combine that water with prepackaged additives to reconstitute parenteral solutions, and package the solutions in sterile IV bags. The Joint Service development contract (USAMRDC acting as lead agency) was issued in May 1986 to deliver Advanced Development Models (ADM) by August 1987 and Engineering Development models by November 1989. Delivery of three systems to the U.S. Army Medical Board was accomplished; however, testing by the AMEDD Board was suspended when the three systems failed to operate satisfactorily. The Concept Evaluation Program (CEP) test is rescheduled for 2Q88. The contractor completed environmental tests and one system was installed and tested aboard the USS Nassau. Technical problems were evident with these ADM models; however, in excess of 2000 bags of solution were produced and packaged.

- A Field Oxygen Generating and Distribution System (FMOGDS) is required for on-site use by TOE hospitals and medical logistics organizations to supply oxygen to patient sites and for filling cylinders. Two developmental contractors (Guild Associates, Inc. and Pall Pneumatic Products, Inc.) completed manufacture and technical testing of prototype units and delivered units to Fort Sam Houston. User tests on these units were conducted and all deliverables have been received at Fort Detrick. A general officer briefing on oxygen status was presented in August 1987, and a Milestone II IPR held on 15 October 1987 recommended remaining in the D/V Phase; extending only one of the existing contracts (Guild); refining the requirements; and procuring Nondevelopmental Items (NDIs) for comparability testing.

- Developments in the Protective Eyewear program have provided significant gains for the ground soldier. Ballistic-Laser Protective Spectacles (B-LPS) which protect against small-mass, low-velocity, flying fragments and low-energy lasers have been evaluated in both laboratory and field tests and determined acceptable by a medical IPR and a nonmedical JWG for initial production. A contract modification for producing 100,000 B-LPS kits was awarded with deliveries scheduled to start on 3 April 1988. Similar eye protection for the aviator in the form of a visor has been demonstrated, and further development for validating production capabilities is ongoing. A suitable optical correction for the M-40 chemical-biological protective mask has produced near- and far-term products. The near-term product is the modified M-17 optical correction, wire version; this has been operationally tested, found acceptable, standardized, and contracted for production. The far-term product makes use of the existing B-LPS prescription lens carrier and is currently undergoing development of an improved mounting system to the mask. Efforts in developing a suitable optical correction for the M-43, M-43 P3I, and other protective masks are continuing.

- The Wheeled Litter Carrier can be used by one person to move patients (casualties) through field medical facilities. A low-rate-initial-production contract negotiated with Associated Tool Company, Inc. for 1964 units will be complete in May 1988. Delivery of the Technical Data Package (TDP) in final form for transition to USAMMA is expected in early 1988.

- The Heater Unit, Patient Holding and Evacuation can be used with existing evacuation bags to provide protection against the cold for casualties during evacuation. A Correspondence IPR on 25 February 1987 recommended an NDI acquisition strategy and requested that the "Heatpac" unit of Norwegian manufacture be standardized. A purchase specification was submitted by USAMMA and a contract was awarded in September 1987. The first Army units to be equipped are in Alaska and should receive the heater units in January 1988.

- The Chemical Warfare Agent Patient Protective Wrap is capable of protecting patients from chemical agents during evacuation in a field environment. The draft report on testing of the Chemical Warfare (CW) Wrap was received from Dugway Proving Ground (DPG) and an Independent Evaluation Report (IER) of testing was prepared. A Milestone III IPR was held in October 1987

and recommended that the product be standardized and transitioned into production and deployment. Additional information from DPG on the test report and delivery of the TDP by U.S. Army Natick Research, Development & Engineering Center (USANRDEC) was promised before the end of 1987.

- A replacement for the Field Refrigerator, Mechanical, Biological (NSN 4410-00-707-2550) is being sought as this unit is no longer logistically supportable. The first independent evaluation on testing of candidate NDI refrigerators was delivered early in 1987. Additional testing was required on temperature stability and the ability to maintain internal temperature without power. These tests were conducted by USABRDL, and the independent evaluation report and market investigation of potential candidate refrigerators were updated. A JGW to recommend selection of a candidate and a correspondence IPR to transition this product to production and deployment is scheduled for early 1988.

- The Litter, Folding, Decontaminable provides a surface on which patients can be decontaminated and which is capable of being easily decontaminated. A final report on the chemical testing of litter cover materials by Battelle Columbus Laboratories was received in April 1987. A TDP is in preparation, and a JWG will be held to consider issues to be resolved prior to a Milestone III IPR.

- The Sterilizer, Steam Vacuum Pulse (SVP) is a ruggedized and highly reliable sterilizer for field hospital use with large through-put, to replace current outmoded units. Award of a new contract for an improved sterilizer system was made to the Castle Company in February 1987, with a 2-year period of performance. Critical Design Reviews were completed, and contractor progress is on track. A TIWG in October 1987 approved the TEMP.

- The Sterilizer, Ethylene Oxide (EOS) is an alternative for sterilizing heat labile surgical supplies using gas. Manufacture of six improved systems was included in a contract award made in February 1987 to the Castle Company. This subsystem will operate independently of the Power Module, but will have many compatible elements with the SVP System, including microprocessor control boards, lift handles, and frame design. Total progress on the EOS/AER project was about 25 percent complete in December 1987.

- The Computer Assisted Post Mortem Identification (CAPMI) is a computerized data base using an MS-DOS operating system and compatible hardware to rapidly match the data of mass casualties to existing dental records. CAPMI will assist forensic teams in rapid identification of post mortem remains by rapidly matching the dental data of casualties against existing dental records stored in a computer data base. There has been extensive field testing using CAPMI with favorable results. A draft Organizational & Operational (O&O) Plan and Required Operational Capability (ROC) have been constructed, but before these documents can go through the approval process, the proponent agencies must be identified. A Logistician must be located, and confirmation of the Quartermaster School as Combat Developer is needed.

- A Powered Ventilator (PV) using an oxygen source for filtered ambient air is required to resuscitate and ventilate casualties on the battlefield or while being evacuated, through either an oropharyngeal mask or a cricothyroid cannula. A draft JSOR was approved at TRADOC in March 1987. An IPR held in June 1987 recommended transition into the D/V phase, and procuring five commercial devices for testing. Devices were procured by July 1987 and a CEP test was conducted at Fort Sam Houston 19-30 October 1987.

- The Resuscitative Device, Individual, Chemical (RDIC) is a manually operated medical device providing positive pressure respiratory resuscitation to assist in the restoration of normal breathing of a battlefield casualty. It is usable with an oropharyngeal mask, or a cricothyroid cannula. A Milestone I IPR moved the product into the D/V phase. NDI devices for testing were procured and testing through December 1987 was approximately 50 percent complete.

- The Cover, Dressing, Patient Field, CW Resistant is designed to prevent penetration of open wounds by chemical warfare agents. The lead agency for development is the U.S. Air Force (Army will monitor). A Milestone III is scheduled for 28 January 1988 to determine the future course of the program.

- The Dental Operating Unit, Field, Portable will provide emergency, limited preventive, and sustaining dental care in the field. Several commercial items are available which meet over 80 percent of the requirements. CEP test results showed that several commercial units performed as well as the developmental item. An IPR is scheduled to resolve conflicts in the LR, and an acquisition strategy decision will be made.

- The X-Ray Unit, Dental, Hand-held is proposed for field use. Delivery of the first National Bureau of Standards prototype was made in December. A draft JSOR was prepared and a System MANPRINT Management Plan (SMMP) was approved. Development of a Baseline Cost Estimate (BCE) was performed and a draft NDI Acquisition Strategy (AS) was written.

- The Calculator, Heat Stress, Hand-Held will predict work/rest cycles or maximal sustainable work cycle, and associated water requirements for the individual soldier under a variety of conditions. The heat stress predictor algorithm can be adapted to any computer system. The AHS has decided to support this product and is currently drafting an O&O Plan. The issue of whether Wet Bulb Globe Temperature (WBGT) technology should be incorporated into this product is under advisement.

- The Monitor, Vital Signs, NBC Casualty noninvasively determines the vital signs of casualties within chemical protective clothing. The Army contractor has developed an instrument which provides heart rate, and blood pressure (systolic, mean arterial, and diastolic), respiration rate, and minute volume in a high vibration and high noise (battlefield) environment. CEP testing was conducted and the test report will be completed in 2Q88. Technical Testing involving humans and baboons will measure consistency and accuracy. The decision to move to advanced development will be made at a Milestone I IPR scheduled for 3Q88.

- The External Rescue Hoist, UH-60 will be externally mounted on the UH-60A (Black Hawk) Medical Evacuation (MEDEVAC) Helicopter. This will provide 25 to 33 percent more space inside the aircraft compared to the internally mounted hoist currently in use providing more cabin space for patient care, medical equipment, and the MEDEVAC litter kit. Decreasing mission time required for the extraction of casualties or personnel will increase survivability of the aircraft and its personnel. A draft O&O plan is now being staffed.

- The Imaging System, Ultrasound for field and shipboard use will be a light unit with archiving on a standard size "floppy" disk. The unit will not only produce an image and store it but also can be used to regenerate an image from the disk. The contractor began integration of system components and obtained images when a problem was encountered with the probe around which the system was designed. This has been resolved with the

subcontractor, and delivery of the first units is expected early in 1988.

- A compact, lightweight, energy efficient CT Scanner, Field system will be capable of producing diagnostic quality CT information in the field. A 2-year contract with three phases is in place. The first phase covers design of the system, fabrication, and testing of the x-ray source and the detector data acquisition testbed. The final product will weigh less than 1600 pounds and require only 10 kW of power. A Market Investigation was completed and a BCE was initiated. A SMMP was approved. The Essential Characteristics (EC) have been defined and are being staffed in preparation for a JWG to develop a draft JSOR.

- An Aeromedical Evacuation System is being evaluated for use in the V-22 aircraft. This aircraft will use tilt rotors to maximize straight and level cruise flight up to 300 knots, yet be able to hover and land. The AMEDD plans for the V-22 to become the primary corps level air ambulance and air vehicle for replenishment of medical personnel, equipment, and supplies from corps to division rear. The Army Surgeon General through USAMRDC will develop the medical package, and an AMEDD panel was convened to review the specific medical requirements contained within the Army's update to the JSOR. In May 1987, the panel was briefed by a Boeing representative to determine which medical requirements contained within the aircraft specifications would be sufficient to meet the AMEDD requirements. Boeing prepared proposals for trade studies for resolution, and the JWG met to review those proposed trade studies. In September, a medical review panel was convened for resolution of major issues and a contract Statement of Work was drafted. A JWG was held in November 1987 to consider revision to the Acquisition Strategy since there are insufficient funds to support this new start. Resolution of the funding and Acquisition Strategy issues and finalizing the Statement Of Work are in progress.

- The Detector, Advanced Life (ALD) is a hand-held device to provide a noninvasive method for detecting heart beat, respiration, or other indicators of life without compromising the chemically protective ensemble or the individual. The name of this product has been changed from "Monitor." A Market Investigation is in progress. A draft JSOR has been submitted to TRADOC. A USAMRDC contract with Purdue University is developing a Personnel Monitor/Communicator similar in shape to a wrist watch. Prototypes for this developmental effort

will be delivered 4Q88. An unsolicited proposal from GMS Engineering to develop a Flash Reflectance Oximeter which measures tissue oxygenation instantly and noninvasively, is being evaluated. A Technology Assessment Plan to summarize military ALD development effort is being produced by USABRDL. Prototypes from developmental efforts will result in a Tri-Service "fly-off."

MAJOR ACCOMPLISHMENTS

- The Norweigan **Patient Holding and Evacuation Heater Unit** was formally transitioned to USAMMA in February 1987.

- The **Chemical Warfare Agent Patient Protective Patient Wrap** was transitioned into production and deployment in October 1987.

- A Milestone III IPR recommended type classification and limited production of the **Military Transportable Field Radiographic and Fluoroscopic System.**

- A Special IPR recommended an interim purchase of 100,000 **Ballistic Laser Protective Spectacle Kits** for contingency troops. A contract modification for producing the kits was awarded in September 1987.

- A Milestone I IPR transitioned the **Powered Ventilator** project into the Demonstration/Validation Phase in June 1987.

- A Milestone I IPR transitioned the **Resuscitative Device, Individual Chemical** into the Demonstration/ Validation Phase in July 1987.

PROJECTIONS

- The **Patient Holding and Evacuation Heater Units** will be delivered to Alaska in January 1988.

- Production of the **Wheeled Litter Carriers** will be be completed in May 1988.

- Delivery of 100,000 **Ballistic Laser Protective Spectacle Kits** for contingency troops will start in April 1988.

- The **Field Medical Refrigerator** will transition to production and deployment in early 1988.

PRESENTATIONS

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Caldwell, Donald W. "Overview of AMEDD Applied Medical Materiel Developer," Advanced Technology Organization of Maryland Looks at Fort Detrick Program, Fort Detrick, Frederick, MD, June 1987.

Clawson, Ronald E. Presentation to U.S.-Israel 1987 Bilateral Military Medical Research and Development Symposium, McLean, VA, August 1987.

Clawson, Ronald E. General Officers Briefing for Representatives from the Republic of Korea, Fort Detrick, Frederick, MD, October 1987.

Clawson, Ronald E. Presentation to Director and Deputy Director, Center for Drug Evaluation and Research, Food and Drug Administration, Rockville, MD, December 1987.

Green, Martin D. "Current Status of Pyridostigmine Development," U.S.-Israel 1987 Bilateral Military Medical Research and Development Symposium, McLean, VA, August 1987.

Harrington, Donald G. "Development of a Safe and Effective Skin Decontamination System," U.S. Army Military Medical Research and Development Symposium McLean, VA, August 1987.

Harrington, Donald G. "Update of USA Development Program for a Safe and Effective Skin Decontamination Kit," NATO, Panel VIII, Research Study Group 3 (RSG-3) Meeting, Gent, Belgium, April 1987.

Harrington, Donald G. "Sustained Release, Oral Pyridostigmine Pretreatment," Skin Chemical/ Biological Operations Symposium, Ft. McClellan, AL, October 1987.

Hillberg, Owen E. "Transdermal Drug Delivery System," Ralph D. Arnold Pharmaceutical Services Seminar, Washington, DC, May 1987.

Hillberg, Owen E. "Challenges in Pharmaceutical Development," Ralph D. Arnold Pharmaceutical Services Seminar, Washington, DC, May 1987.

Hillberg, Owen E. "Morphine Repackaging," Office of The Surgeon General, Army Medical Department Technical Committee, Washington, DC, December 1987.

Jacob, Willis H. "Development of the Multidose Autoinjector," Office of The Surgeon General, Army Medical Department Technical Committee, Washington, DC, June 1987.

Jacob, Willis H. "Product Evaluation of the Dual Barrel Autoinjector, MARK II," Sixth Medical Chemical Defense Bioscience Review, Columbia, MD, August 1987.

Lehmann, Craig R. "Efficacy of Intramuscular Diazepam for Status Epilepticus," Uniformed Services University of the Health Sciences, Bethesda, MD, November 1987.

Lehmann, Craig R. Presentation to Director and Deputy Director, Center for Drug Evaulation and Research, Food and Drug Administration, Washington, DC, December 1987.

Lehmann, Craig R. "Nerve Agent Anticonvulsant," Office of The Surgeon General, Army Medical Department Technical Committee, Washington, DC, December 1987.

Nielsen, Carl J. "Improved BAL (I-BAL) for Ophthalmic Use," Office of The Surgeon General, Army Medical Department Technical Committee, Washington, DC, December 1987.

Oaks, Stanley C., Jr. Information briefing to TRADOC TSARC Working Group, at OTEA, Falls Church, VA, on USAMRDC Outline Test Plans (OTP) requiring access to volunteers, April 1987.

Oaks, Stanley C., Jr. Decision briefing to General Officer TSARC at OTEA, Falls Church, VA, to allow USAMRDC to participate in the OTP process to volunteers for clinical trials, June 1987.

Oaks, Stanley C., Jr. Information briefing to AMEDD Pre-TSARC Working Group, at USAMMDA, on Biological Systems Division test issues, July 1987.

Oaks, Stanley C., Jr. Decision briefing to Commanding General, I Corps, at Fort Lewis, WA, on proposed Hepatitis A Phase II clinical trial, September 1987.

Oaks, Stanley C., Jr. Information briefing to Deputy Assistant, DCSOPS, at the Pentagon, to resolve Shigella Capstone JSOR issues, December 1987.

Popek, Donna K. Moderator for Federal Women's Program panel discussion on Career Enhancement, Fort Detrick, Frederick, MD, May 1987.

Wannarka, Gerald L. Briefing to DOD Health Affairs on DOD-FDA MOU, Washington, DC, February 1987.

Wannarka, Gerald L. Program Briefing to military delegation from Republic of Korea, Fort Detrick, Frederick, MD, July 1987.

Wannarka, Gerald L. U.S.-Israel 1987 Bilateral Military Medical Research and Development Symposium (Moderator), McLean, VA, August 1987.

Wannarka, Gerald L. Presentation to Director and Deputy Director, Center for Drug Evaluation and Research, Food and Drug Administration, Washington, DC, December 1987.

PUBLICATIONS

Hillberg, Owen E. "Pharmacy Practice in the United States Army," Vol. 44, April 1987, p. 755, American Journal of Hospital Pharmacy.

SEMINARS

Beahm, Michael R. American Pharmaceutical Association, San Francisco, CA, March 1987.

Beahm, Michael R. Ralph Arnold Pharmaceutical Services Seminar, Washington, DC, May 1987.

Beahm, Michael R. American Society of Hospital Pharmacists, Atlanta, GA, December 1987.

Brandt, Walter E. WHO Steering Committee on Dengue, reviewing contract submissions for vaccine production, Geneva, Switzerland, June 1987. (Named Chairman of this Committee, August 1987, for 3-year term.)

Brandt, Walter E. Chaired WHO symposium on Current Approaches for the Development of Dengue Vaccines and Related Aspects of the Molecular Biology of Flaviviruses, Edmonton, Canada, August 1987.

Brandt, Walter E. VII International Congress of Virology, Edmonton, Canada, August 1987.

Brandt, Walter E. American Society of Tropical Medicine and Hygiene Annual Meeting, Los Angeles, CA, November 1987. (Chaired session on rapid identification; participation in committee meeting on antigenic classification of vector transmitted viruses; on Scientific Program Committee.)

Clawson, Ronald E. Third International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, February 1987.

Clawson, Ronald E. Sixth Medical Chemical Defense Bioscience Review, Columbia, MD, August 1987.

Clawson, Ronald E. U.S. Israel 1987 Bilateral Military Medical Research and Development Symposium, McLean, VA, August 1987.

Clawson, Ronald E. Joint Services Review of Man-Monkey Dose Equivalency Studies for Atropine, San Antonio, TX, December 1987.

Hawley, Robert J. Advanced Technologies for CB Detection, Chemical Research, Development and Engineering Center, Aberdeen Proving Ground, MD 1 April 1987.

Hawley, Robert J. Leishmaniasis Diagnosis, WRAIR, Washington, DC, May 1987.

Hawley, Robert J. Detection of T-2 Mycotoxin and its Metabolites in Urines of Exposed Rats. Comparison of a potentially fieldable kit with a laboratory assay, USAMRIID, Fort Detrick, Frederick, MD, September 1987.

Hawley, Robert J. Conference on Military Medicine, USUHS, Bethesda, MD, October 1987.

Johnson-Winegar, Anna. Joint Technical Coordinating Group/Combat Casualty Care, Fort Sam Houston, TX, April 1987.

Johnson-Winegar, Anna. Blood Substitute Symposium, Montreal, Canada, May 1987.

Johnson-Winegar, Anna. Antiviral Drug Review Seminars, Omni Shoreham Hotel, Washington, DC, August 1987.

Johnson-Winegar, Anna. Society for Industrial Microbiology, Baltimore, MD, August 1987.

Johnson-Winegar, Anna. U.S. Israel 1987 Bilateral Military Medical R&D Symposium Science Applications International Corporation (SAIC), McLean, VA, August 1987.

Johnson-Winegar, Anna. 27th Interscience Conference on Antimicrobial Agents and Chemotherapy, New York, NY, October 1987.

Johnson-Winegar, Anna. Infectious Disease Society of America meeting, New York, NY, October 1987.

Lightner, Lawrence K. OCONUS Lab Commanders Conference, Bethesda, MD, November 1987.

Lightner, Lawrence K. American Society of Tropical Medicine and Hygiene Annual Meeting, Los Angeles, CA, November 1987.

Oaks, Stanley C., Jr. Society of Armed Forces Medical Laboratory Scientists Annual Meeting, Baltimore, MD, February 1987.

Oaks, Stanley C., Jr. Large-Scale Bioprocessing Safety Symposium, Washington, DC, October 1987.

Oaks, Stanley C., Jr. Conference on Military Medicine, USUHS, Bethesda, MD, October 1987.

Pick, Robert O. Joint Services Infectious Disease Research Lab Commanders Conference, Bethesda, MD, November 1987.

Popek, Donna. Fifth Annual Federal Women's Program Conference, Fort Meade, MD, September 1987.

Roberts, Lyman W. American Society of Tropical Medicine and Hygiene Annual Meeting, Los Angeles, CA, November 1987.

Twist, Anne P. Policy Issues for 1987 Conference, National Association of Business Economists, Washington, DC, February 1987.

Twist, Anne P. Annual Operations Research Symposium AORS XXVI, Ft. Lee, VA, October 1987.

Wannarka, Gerald L. U.S. Army Medical Research Institute of Chemical Defense Vesicant Workshop, Aberdeen Proving Ground, MD, February 1987.

Wannarka, Gerald L. American Pharmaceutical Association, San Francisco, CA, March 1987.

TRAINING

Bateman, Edgar. Human Factors Engineering, Ann Arbor, MI, August 1987.

Brandt, Walter E. Improving Performance Standards, Training Center, Fort Detrick, Frederick, MD, February 1987.

Brandt, Walter E. Privacy Act Training, Strough Auditorium, Fort Detrick, Frederick, MD, October 1987.

Caldwell, Donald W. LOTUS 1-2-3/MS-DOS, Traning Center, Fort Detrick, Frederick, MD, August 1987.

Channing, Eugene S. AMEDD Field Optometry Course, Aurora, CO, March 1987.

Clawson, Ronald E. Introduction to Armed Forces Medical Intelligence, Fort Detrick, Frederick, MD, April 1987.

Clawson, Ronald E. Advanced Concepts in Cost Estimating, Baltimore, MD, June 1987.

Green, Martin D. Materiel Acquisition Management Class ALMC, Ft. Lee, VA, October-December 1987.

Harshman, Robert E. Security and Automated Systems, ALMC-DX, Ft. Lee, VA, February 1987.

Harshman, Robert E. Improving Performance Standards, Training Center, Fort Detrick, Frederick, MD, February 1987.

Harshman, Robert E. EEO Law for Managers and Supervisors, Training Center, Fort Detrick, Frederick, MD, September 1987.

Harshman, Robert E. Security and Automated Systems, Wilson College, Chambersburg, PA, December 1987.

Hathaway, Cecil C. Lotus 1-2-3 - MS/DOS Introduction for New Microcomputer Users, USAISC Training Center, Fort Detrick, Frederick, MD, August 1987.

Hathaway, Cecil C. Microprocessor Programs and Methods for Integrated Logistic Support, University of Maryland, College Park, MD, September 1987.

Hawley, Robert J. TRADOC Test Officer's Orientation Course, Fort Detrick, Frederick, MD, January 1987.

Hawley, Robert J. Rapid Testing for Infectious Diseases; American Society for Microbiology Workshop, Atlanta, GA, February 1987.

Hawley, Robert J. Written and Verbal Techniques for Successful Communication; American Management Association (Saranac Lake, New York), Washington, DC, December 1987.

Jacob, Willis H. Source Evaluation and Selection, Washington, DC, September 1987.

Johnson-Winegar, Anna. FDA Seminar on New IND Rules, Washington, DC, June 1987.

Johnson-Winegar, Anna. AMA Course for New Supervisors, AMA Management Center, Washington, DC, July 1987.

Johnson-Winegar, Anna. EEO Training for Supervisors, Training Center, Fort Detrick, Frederick, MD, September 1987.

Johnson-Winegar, Anna. Privacy Act Training, Fort Detrick, Frederick, MD, October 1987.

Jones, Jerry L., Jr. IBM/MS-DOS: An Introduction, GSA Training Center, Arlington, VA, June 1987.

Jones, Jerry L., Jr. Lotus 1-2-3: Advanced, GSA Training Center, Arlington, VA, June 1987.

Jones, Jerry L., Jr. IBM/MS-DOS: Advanced, GSA Training Center, Arlington, VA, July 1987.

Lightner, Lawrence K. Lotus 1-2-3/MS-DOS Training Course at USAISC Training Center, Fort Detrick, Frederick, MD, August 1987.

Lightner, Lawrence K. Privacy Act Training, Fort Detrick, Frederick, MD, October 1987.

Nielsen, Carl J. IND Rewrite and the Treatment, Use, and Sale of Investigational Drugs, Rockville, MD, May 1987.

Nielsen, Carl J. Source Evaluation and Selection, Washington, DC, September 1987.

Nielsen, Carl J. Ophthalmic Drug Delivery, East Brunswick, NJ, September 1987.

Nielsen, Carl J. Research and Development Orientation, Ft. Lee, VA, November 1987.

Oaks, Stanley C., Jr. TRADOC Combined Arms Test Activity (TCATA) Test Officer's Orientation Course, USAMMDA, January 1987.

Oaks, Stanley C., Jr. Lotus 1-2-3/MS-DOS Training Course, USAISC Training Center, Fort Detrick, Frederick, MD, August 1987.

Oaks, Stanley C., Jr. OTEA OTP Software (OTIS) Training Course, USAMMDA, November 1987.

Oaks, Stanley C., Jr. Program Manager's Briefing Course, DSMC, Fort Belvoir, VA, December 1987.

O'Connor, Richard J. Digital Imaging Conference, The Presidio of San Francisco, CA, April 1987.

O'Connor, Richard J. Parylene 87 Technology Update, Indianapolis, IN, April 1987.

O'Connor, Richard J. Principles and Applications of Value Engineering, Rock Island, IL, July 1987.

O'Connor, Richard J. Lotus 1-2-3/MS-DOS, Fort Detrick, Frederick, MD, August 1987.

Parra, Deanna W. Image and Self-Projection for Professional Women, Sheraton Inn, Hagerstown, MD, May 1987.

Perry, Ray H. Improving Performance Standards, Training Center, Fort Detrick, Frederick, MD, February 1987.

Popek, Donna K. Image and Self-Projection for Professional Women, Sheraton Inn, Hagerstown, MD, May 1987.

Popek, Donna K. Lotus 1-2-3/MS-DOS Training Course, USAISC Training Center, Fort Detrick, Frederick, MD, August 1987.

Popek, Donna K. EEC for Advisory Council Members, Training Center, Fort Detrick, Frederick, MD, September 1987.

Popek, Donna K. Privacy Act Training, Fort Detrick, Frederick, MD, October 1987.

Priebe, Rebecca A. Image and Self-Projection for Professional Women, Sheraton, Inn, Hagerstown, MD, May 1987.

Priebe, Rebecca A. Microcomputers: IBM-PC/MS-DOS, Frederick Community College, Frederick, MD, 28 May - 18 June 1987.

Priebe, Rebecca A. Upgrade, Repair, Maintenance, and Troubleshooting of PCs, Peabody Court Hotel, Baltimore, MD, 29 June - 1 July 1987.

Priebe, Rebecca A. Lotus 1-2-3/MS-DOS Introduction for New Microcomputer Users, USAISC Training Center, Fort Detrick, Frederick, MD, August 1987.

Priebe, Rebecca A. VAX/VMS Operator Training, Digital Equipment Corp., Landover, MD, October 1987.

Pyne, Frederick M. How to Make MIL-STD-810D Work, Anaheim, CA, March 1987.

Pyne, Frederick, M. Symposium for Innovation In Measurement Science, Geneva, NY, August 1987.

Roberts, Lyman W. Lotus 1-2-3/MS-DOS Training Course, USAISC Training Center, Fort Detrick, Frederick, MD, August 1987.

Roberts, Lyman W. Privacy Act Training, Fort Detrick, Frederick, MD, October 1987.

Rose, Thomas M. Stress Management Training for Administration, Technical, and Professional Personnel, Training Center, Fort Detrick, Frederick, MD, April 1987.

Salisbury, Lloyd L. Lotus 1-2-3/MS-DOS, Fort Detrick, Frederick, MD, August 1987.

Sheffer, Linda J. Managerial Cost Accounting, Frederick Community College, Frederick, MD, January-May 1987.

Sheffer, Linda J. Power Communication Skills for Women, Sheraton Inn, Hagerstown, MD, March 1987.

Sheffer, Linda J. Memory Development and Effective Listening, Training Center, Fort Detrick, Frederick, MD, May 1987.

Sheffer, Linda J. Budget Estimating Techniques, Training Center, Fort Detrick, Frederick, MD, June 1987.

Sheffer, Linda J. Intermediate Accounting III, Frederick Community College, Frederick, MD, August - December 1987.

Sheffer, Linda J. Lotus 1-2-3/MS-DOS Introduction for New Microcomputer Users, USAIC Training Center, Fort Detrick, Frederick, MD, August 1987.

Sheffer, Linda J. How to Make Presentations That Win Approval, Ramada Inn Convention Center, Hagerstown, MD, November 1987.

Sullivan, Clara V. English Composition and Literature, Frederick Community College, Frederick, MD, January - May 1987.

Sullivan, Clara V. Administrative Correspondence, Training Center, Fort Detrick, Frederick, MD, March 1987.

Sullivan, Clara V. Better Office Skills and Services, Training Center, Fort Detrick, Frederick, MD, May 1987.

Sullivan, Clara V. Speech Fundamentals, Frederick Community College, Frederick, MD, August - December 1987.

Twist, Anne P. Power Communication Skills for Women, Sheraton Inn, Hagerstown, MD, March 1987.

Twist, Anne P. Business Managers Course Defense Systems Management College, Ft. Belvoir, VA, 26 April - 15 May 1987.

Twist, Anne P. Lotus 1-2-3, Fort Detrick, Frederick, MD, August 1987.

Twist, Anne P. How to Make Presentations That Win Approval, Marriott, Gaithersburg, MD, November 1987.

Twist, Anne P. Stress Management Strategies For Women, Holiday Inn, Bethesda, MD, December 1987.

Tucker, Betty J. Power Communication Skills for Women, Sheraton Inn, Hagerstown, MD, March 1987.

Tucker, Betty J. How to Make Presentations That Win Approval, Ramada Inn Convention Center, Hagerstown, MD, November 1987.

Via, Annette G. Better Office Skills and Service, Training Center, Fort Detrick, Frederick, MD, May 1987.

Via, Annette G. ADP for Administrative, Secretarial, and Clerical Personnel, Training Center, Fort Detrick, Frederick, MD, July 1987.

Wannarka, Gerald L. IND Rewrite and the Treatment, Use, and Sale of Investigational Drugs, Rockville, MD, June 1987.

Zajac, Andrew J. Principles of Acquisition For Contracting Representatives Course, Alexandria, VA, March 1987.

Zajac, Andrew J. Human Factors Engineering Course, Ann Arbor, MI, August 1987.

Zajac, Andrew J. Biomedical Information System Officer (67D) Course, Quality Inn, Frederick, MD, September 1987.

Zittle, Virginia L. Effective English Workship, Training Center, Fort Detrick, Frederick, MD, February 1987.

Zittle, Virginia L. Better Office Skills and Service, Training Center, Fort Detrick, Frederick, MD, May 1987.

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